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Project Number: 101057390

Project Acronym: HappyMums

Project title:

Understanding, predicting, and treating depression in pregnancy to improve mothers and offspring mental health outcomes.

D9.1 Dissemination and Exploitation plan

Research and Innovation Action

HORIZON-HLTH-2021-STAYHLTH-01-02

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Executive Summary

This version of the *HappyMums* Dissemination and Exploitation plan serves as a management tool to define the dissemination and exploitation framework and guidelines for the whole project consortium. It will be used as a reference document during the project duration, including for regular monitoring and evaluation. Depending on project progress and external factors, the dissemination and exploitation plan will be updated and adapted to fit the needs of, and to deliver the best possible results for *HappyMum*.

This plan aims to identify and organise the activities to be performed to maximise the impact of the project and to communicate its benefits to the targeted stakeholder communities, which range from biomedical scientists and clinicians, to public agencies, mothers and mothers-to be and the general public.

To achieve this goal, this plan defines : a) strategic goals, communication messages, KPI's and means of verification; b) project visual identity (the logo and templates), as well as editorial standards in public and stakeholder dissemination, including the consortium website, the social media accounts, and multiple stakeholder-specific newsletters; c) detailed working plan containing activities, timescales, responsibilities, processes for sharing and utilization of the data, peer-review and approval of reports and publications, and archiving and open access of papers.



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Acronyms

Abbreviation	Full term	
ACNP	American College of Neuro-psychopharmacology	
AI	Artificial Intelligence	
AMR)	Academy of Behavioral Medicine Research	
ASHG	American Society of Human Genetics	
СА	Consortium Agreement	
ECNP	European College of Neuropsychopharmacology	
ESHG	European Society of Human Genetics	
EU	European Union	
GA	General Assembly	
ISPNE	International Association for Psychoneuro-endocrinology	
KER	Key Exploitable Results	
KPI	Key Performance Indicator	
PAS	Pediatric Academic Societies	
PC	Project Coordinator	
PM	Project Manager	
RIA	Research and Innovation Action	
SC	Steering Committee	
SESAB	Scientific, Ethical and Social Advisory Board	
SfN	Society for Neuroscience	
SOBP	Society for Biological Psychiatry	
TC	Teleconference	
WHO	World Health Organization	
WP	Work Package	
WPL	Work package Leader	



1 Introduction

Perinatal mental disorders contribute enormously to societal and health burdens, both during pregnancy and beyond. According to the World Health Organization (WHO) data, depression is the most common mental health disorder in pregnancy, affecting between 10% and 15% of pregnant women. In turn, a mother's mental health and wellbeing may affect their child's development. Stress, depression and anxiety during and after pregnancy is associated with disturbances in childhood development.

HappyMums will be the first EU project specifically designed to improve our understanding on the biological mechanisms underlying the development of depressive symptoms in pregnancy, and the efficacy of interventions. *HappyMums* will also identify the mechanisms that affect the fetal environmental biology, shaping offspring risk for developing negative mental outcomes later in life. Further, we will identify the prenatal and postnatal factors that exacerbate, or buffer, the risk shaped in utero. The *HappyMums* consortium will also develop a digital platform where different biomarkers (AI tools-based data integrated with biological, clinical, medical, environmental and lifestyle data) will be collected through a mobile phone app that will be at the interface with clinicians. This will allow early screening of depressive symptoms, prompt diagnoses, personalized treatments, and the promotion of protective lifestyle attitudes. Importantly, by improving mental health in mothers, *HappyMums* will provide unpreceded benefits also to the offspring and thus to society at large.

In order to achieve these ambitious impacts, *HappyMums* plans to structure a dissemination strategy aimed at making key project results available to key audiences at the right point all along its lifetime, seeking efficiency and cost effectiveness.

To this end, much attention has been given to the interaction with external actors, policy makers and stakeholders, ensuring the value of the final results and recommendations.

The table below (Table 1) describes the logical steps towards the achievement of the expected impacts of *HappyMums* over time, considering also the post-project period. The pathway begins with the projects' results, to their dissemination, exploitation and communication, contributing to the expected outcomes in the work programme topic, and ultimately to the wider scientific, economic and societal impacts of the work programme destination.



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Table 1. Key elements of HappyMums impact pathway and of the measures to maximise its impact.

Specific Needs	Expected Results	Dissemination, Exploitation & Communication measures
 Need improved knowledge on mechanisms triggering depression development in pregnancy and how they affect the foetal environment leading to negative mental outcomes in offspring. No multimodal heterogeneous biomarkers are integrated at individual level for risk prediction and treatment response. No AI based biomarkers are used in the clinical setting No empowering tool is available for clinicians and pregnant women to monitor depressive symptoms. New strategies to prevent the onset of depressive symptoms in at risk women are needed in the clinical setting. Integrative strategies to reinforce mental well-being in pregnant women are missing. 	 Increased knowledge in the field of Depression in pregnancy Novel biomarkers in the mother (i.e maternal blood signatures) during pregnancy associated with depressive symptoms onset and progression and with response to treatments. Novel biomarkers in the offspring (i.e. DNA methylation) exposed to maternal depression of the risk for the transition toward negative mental outcomes during childhood and adolescence. New targets for future treatments to prevent or manage the onset of depressive symptoms in pregnant women. Algorithm for composite score integrating the different markers to compute 1) the risk for mothers to develop depressive symptoms during pregnancy and 2) the response to treatments. New digital platform to daily collect information from pregnant women to monitor and reinforce or modify their lifestyle. Proof of concept for future treatments to prevent or manage the onset of depressive symptoms in pregnant women. 	 Dissemination towards the scientific community: Publication of 5 scientific articles; Organization of 6 dedicated symposia and 3 scientific events; One open access research platform. Dissemination towards clinical community and health policymakers: Organization of 2 external events and 2 workshops on the clinical and social outcomes of the project Exploitation of identified biomarkers: patents to be licensed out to biotech companies and pharma. Exploitation of novel targets: 2 meetings with biotech companies and pharma to develop novel targets. Exploitation of the AI platform (smartphone app, new tools etc) for its adoption among mothers, clinicians, and GPs. Communication towards citizens: 4 press releases and 3 articles on lay media. Collaboration with other (EC-funded) projects: link with at least 2 EU complimentary projects for concertation.
Target Groups	monitoring Outcomes	Impacts
 Scientific Community: basic scientists, clinical scientists, Al experts, bioinformatics, and decision-support software developers. Clinicians and health professionals interacting with pregnant women (or that are planning to have a baby) with mental illness. Private and public investors supporting the development of new innovative tools for screening, early -risk detection, interventions, and treatment monitoring. Public agencies and patients' associations working on reducing the impact and the stigma of depression in pregnancy, especially in terms of prevention policies and clinical guidelines. Pregnant women suffering from depression and that are planning to have a baby, pregnant women with depressive symptoms or at risk Citizens interested in mental health. Pharmaceutical companies producing and/or developing or repurposing already existing medicines 	 High use of the scientific published discoveries (measured with citations of publications). Use of algorithm for risk prediction and for treatment response prediction by clinicians and GPs. Women, psychiatrists, and clinical psychologists in different countries will be provided with an integrative tool to prevent and monitor depressive symptoms in pregnancy. Psychiatrists and clinical psychologists will be proposed to use a digital platform for a continuous monitoring of depressive condition in pregnant women. New targets will be identified and provided to companies for the development of new drugs, or for the repurposing of medicines targeting the identified pathways Develop recommendations and promote lifestyle attitudes for a better management of mental health condition in pregnant, women Reduce the stigma and worries in women that suffer of depression and want to have a baby. 	 Scientific: New breakthrough scientific discovery on mechanisms underlying the development of depressive symptoms in pregnancy, the efficacy of interventions, the role of foetal environment on the development of negative outcomes in the exposed offspring. Role of prenatal and postnatal factors. Economic/Technological: Reduction of costs linked to the management of depressive symptoms in pregnancy; reduction of the cost associated with the management of children from mums that had depression in pregnancy and with high probability also during child development. New market for treatments allowed in pregnancy. New market for biomarker assay and clinical decision support tool. Social: Reduction of social burden linked to depression in pregnancy and to its consequences on the offspring. Empowerment of women to monitor and manage their mental health. Improve the adoption of healthier lifestyles and behaviors preventing depression in pregnancy and its consequences to the offspring. Reduced stigma associated to depression in pregnancy. Reduced worry in taking medications.

2 Dissemination

HappyMums will explore new territories at the interface between fundamental and clinical research by addressing the medically important issue associated with the development of depressive symptoms in pregnancy and their impact on mothers and, as consequences, to their exposed offspring.

For *HappyMums*, effective dissemination and the acquisition of scientific credibility will have a fundamental role to achieve this vision. This way, *HappyMums* can exploit the opportunity offered by unified statistical simulation models to bring consistent and expert diagnosis and prognosis beyond clinics specialized in perinatal mental health to a wider range of general hospitals and health centres.

Moreover, dissemination and communication activities are crucial to ensure continuity to *HappyMums* results after the end of the project, since the creation of a worldwide community of individuals and institutes from different scientific and clinical communities interested in using *HappyMums* results is an essential step for commercial exploitation and business development. The modalities to develop the sustainability of the project will be detailed in dedicated deliverables (D9.2 Exploitation and Business plan v1 and D9.5 Exploitation and Business plan v2).

Finally, in the longer term, if correctly and extensively disseminated, the modelling approaches developed in *HappyMums* will lay the methodological foundation for new personalised medicine approaches also outside the context of perinatal mental health.

The *HappyMums* dissemination and communication strategy is designed to spread the results of *HappyMums* scientific and technology development and to attract a larger and active user community of researchers, clinicians and women that might consider to get involved in *HappyMums* and to pave the way for a possible and future adoption of its tools in the application domain, perinatal mental health , and beyond, being the unified statistical simulation models developed in *HappyMums* a first step towards a radical paradigm shift in the wider medical field.

The plan will thus expand in two directions:

• towards the widening of the user base of the tools developed during *HappyMums* (i.e. the Algorithm for composite risk score and the new digital platform, to daily collect information from pregnant women to monitor and reinforce or modify their lifestyle) in order to enhance the diffusion potential of the system;



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towards the promotion, in the scientific and clinical sectors, of the transformational shift that *HappyMums* can bring into our diagnostic system using a bottom-up approach based on the integration of heterogeneous digital and biological data, instead of the current top-down approach centered on our limited classification system.

2.1 Dissemination steps

The approach to dissemination in *HappyMums* can be represented as an adapted version of the "principle of the Five Ws" (Who, What, Why, When and How)

STEP 1	Who	The person or team in charge of specific activities, taking into consideration partners' skills and expertise.	
STEP 2	Why?	The aim the Consortium likes to achieve	
STEP 3	To Whom?	The main beneficiaries and target groups of dissemination actions.	
STEP 4	What?	What the consortium should do in order to maximize the impact of the project, both within and beyond the participants and their countries.	
STEP 5	How	The channels, instruments and tools to conceive, design and implement how to expand at large project objectives and results, methods and practices.	
STEP 6	When?	The timeline of dissemination and communication activities, taking into account project progress and achievements.	

Dissemination Step 1: Dissemination actors (WHO)

All *HappyMums* partners contribute to dissemination activities. By having on board numerous leading scientists from the field of neuroscience as well as senior clinical experts, the *HappyMums* consortium, which has also a great geographical spread, is outstandingly connected very well with its scientific/clinical audience.

Indeed, the dissemination of results will be greatly facilitated by the existing links of *HappyMum* members to leading national and international organizations, such as the European College of Neuropsychopharmacology (ECNP), the American College of Neuropsychopharmacology (ECNP), the American College of Neuropsychopharmacology (ACNP), the International Association for Psychoneuroendocrinology (ISPNE), the American Society of Human Genetics (ASHG), the European Society of Human Genetics (ESHG), the Society for Biological Psychiatry (SOBP), the Academy of Behavioral Medicine Research (ABMR), the Society for Neuroscience (SfN) and the Pediatric Academic Societies (PAS). This means that *HappyMums* results can be presented at the annual meetings of these societies. Moreover, since many *HappyMums* partners have executive roles in these societies, whenever possible, we will propose symposia and workshop dedicated to *HappyMums* research at such meetings.





Moreover, Tommy's and the Marcé Society, a charity patient association and a research patients' association, will ensure to target women and convey the appropriate messages to families.

Finally, the Scientific, Ethical and Social Advisory Board (SESAB) will provide (un)solicited advice regarding dissemination throughout the project.

Dissemination Step 2: Dissemination and communication objectives (WHY?)

The specific *HappyMums* dissemination objectives for the project duration are:

- 1. illustrate the benefit of *HappyMums* tools for disease understanding, where the primary mechanisms are scientific publications and the Research Platform with tools, data, protocols, and publications developed in WP2.
- 2. Illustrate the benefit of the *HappyMums* digital platform (Clinical Digital Platform) using the new identified biomarkers, where dissemination through scientific publications and presentations is supported by the federated learning tools made open-source and distributed to the community working in maternal/child health research.
- 3. Promote the adoption of the *HappyMum* digital platform (mobile App&clinical dashboard) for predicting disease progression and for interventions efficacy toward women and clinicians.
- 4. Reduce stigma against depression in pregnancy by improving and sharing knowledge about the molecular and neurobiological basis of mental health in pregnancy and by empowering women to take control of their own health.
- 5. Increase the number of *HappyMums* consultation partners and supporters, especially big players such as Private and public investors and public agencies to promote sustainability in the long-term. The clinical partners and the SESAB members will further facilitate this process through their involvement in various committees that set clinical regulations and diagnostic guidelines, as well as their involvement in clinical trials.
- 6. Increase awareness among the general public and concerned stakeholders on *HappyMums* value and impact on reducing cost and enabling effective therapy development.

Dissemination Step 3: Stakeholder analysis (WHO/to WHOM?)

HappyMums is expected to raise significant interests across a wide range of stakeholders. At the moment, these target groups have been identified:



Table 2. List of Stakeholders and their Interest

Stakeholders	Interest	
Clinical Scientists	Clinical, medical lifestyle features and peripheral biomarkers mapping the development of depressive symptoms in pregnancy.	
Basic Scientists	Molecular mechanisms leading to depression in pregnancy; <i>in utero</i> programming; neurodevelopmental trajectories associated with the development of a vulnerable or resilient phenotype in offspring exposed to in utero depression.	
Clinicians and GPs	Clinical tools in pregnancy for screening, prevention, treatment, and monitoring; Decision support software.	
SME and Industries	Drug discovery research; kits for biomarkers detection; Digital Tools.	
Technical researchers & technologists	Data management, bioinformatics, machine learning and decision support software development.	
Private and public investors	Development of innovative tools for screening, risk identification and interventions	
Public agencies	Reduction of the impact of mental health, especially in terms of prevention policies and clinical guidelines.	
Women and families	Tools for a better mental health dedicated to women and to their perinatal journey	

Dissemination step 4: Definition of messages and contents (WHAT?)

Having defined the relevant stakeholders, the next step is the definition of the content and messages to generate the materials adapted to each stakeholder group. Here the main dissemination objectives and related messages.

Establish future clinical research directions

Unveil the biological pathways and biomarkers to map and monitor depressive symptoms in pregnancy

Link the presence of depressive symptoms in pregnancy with altered biology at foetal environment.

Identify prenatal moderators of the development of depressive symptoms in pregnancy.

Identify postnatal moderators of the risk for negative outcomes in the exposed offspring.

Promote the use of biomarkers in the clinical setting.

Point towards tools for better prevention and diagnosis, and management of depressive symptoms.

Promote research in the domain of resilience, by targeting specific biological pathways.

Stress the importance of the integration of multi-level/multi-omics approaches at individual level.

Accelerate innovation and technology transfer

Disseminate machine learning approaches for predictive modelling.

Provide new multimodal biomarkers for screening, monitoring and treatment response in pregnancy.



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Prove the utility of AI-based biomarkers & early signs detection for depression in pregnancy.

Promote a digital platform completely dedicated to pregnant women for monitoring and self-help.

Promote investments for leveraging the new identified biomarkers (e.g.in maternal blood).

Point to druggable pathways for drug development or drug repurposing.

Provide novel targets for the development of novel interventions.

Positively influence women and families

Change knowledge on the risk and protective factors associated with perinatal mental disorders

Promote active engagement of women and adherence to effective strategies.

Promote the adoption of lifestyle attitudes to improve health outcomes in pregnancy.

Raise awareness on the importance of prevention in pregnancy to reduce burden of major diseases.

Highlight the need of improving mental health in pregnant women as this will benefit their children.

Reduce health and care disparities due to socioeconomic status.

Improve clinical guidelines and prevention

Promote the introduction of mental health screening for pregnant women and early risk estimation.

Allow improved allocation of social and clinical resources (e.g. towards high-risk groups).

Show the relevance of biomarkers in personalized patient stratification, screening and treatment.

Improve communication between medical specialties (e.g. psychiatry and gynecology).

Specify the role of environmental and lifestyle factors.

Pave the way for a new generation of practitioners able to use digital tools.

Dissemination step 5: Definition of channels (HOW?)

The dissemination channels are the means through which the project will communicate with the target audiences. *HappyMums* aims to 'think outside the box' in regard to communication and will explore all available modern tools and technologies, such as social media, to interact with its audiences, create awareness and maintain positive public relations.

Table 3. List of KPIs and Key channel

Dissemination Channels/Target Groups (TG)/ KPIs	Key channel
<i>HappyMums</i> Website TG: Scientific and general public (including policymakers). KPI: N. of hits (>2000 by the end of Y1; >3600 by the end of project),	The <i>HappyMums</i> website is now online and will be maintained by UMIL with continuous updates. English is the official language, but core sections will be translated and reported into partners' local resources.
Scientific Articles TG: Scientific community. KPI: 8 papers in 4 years, 1 special issue.	Publication of Scientific articles in open access international peer-reviewed journals adhering to the EC Open Access policy.

Outputs for the media and the public TG: General public KPI: at least 10 outputs over 4 years	Press engagement, at national and international level, to disseminate key findings after publication of papers, of reports and of recommendations. Generation of media and public outputs, as either interviews in newspapers, TV or radio channels, or as directly produced blogs, articles in the press, podcasts and videos, also linked with the Final Workshop (see below).
Dissemination events TG: All. KPI: N° of external experts (5 experts x meeting); N° of stakeholders involved (3 different types x meeting)	Organization of 2 dedicated workshops to share results, collect feedback and build new synergies as satellite events/parallel sessions during relevant conferences (e.g ECNP annual meeting). The Final workshop will include discussions of follow-up ideas and initiatives to maximise the project impact. The event will involve a wide variety of stakeholders: members of scientific communities, policymakers (from national/international institutions) to present the main project outcomes. A press conference will be set to attract media from EU.
External Events TG: Scientific community, practitioners, policymakers. KPI: at least 3 x core partner	Dissemination of <i>HappyMums</i> results by presentations, stands and seminars taking advantage of the involvement of partners in several scientific societies (e.g. ECNP, SOBP, ACNP).
Liaison activities with other EU projects TG: Scientific community, practitioners, policy- makers. KPI: 5 EU projects addressed, at least.	Liaising with international, EU-wide, national, and regional related projects exchanging good practices and ideas and collecting feedback on results; Particular attention is being paid to projects funded within other Horizon Europe Cluster 1 calls which could be of relevance.

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Dissemination step 6: Dissemination and Communication timelines (WHEN?)

Since, as described above, *HappyMums* dissemination activities have different objectives and targets, the focus will be on the tools which engage the recipient in a process whether it is one of increased awareness, support, involvement and commitment.

In order to achieve these objectives, 4 temporal phases regarding dissemination and publication have been identified according to the expected level of user involvement.

• <u>Planning Phase</u>: During the first year of *HappyMum*, the focus on the needs to be on the definition of strategic plans. Moreover, effort has been and will be devoted to the definition a unique and comprehensive identity for *HappyMums* and to lay

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dissemination which consisted in creating project tools (web portal, project presentation, internal mailing lists, project templates) for target audiences that do not require a detailed knowledge of *HappyMums* tools but want to be aware of activities and outcomes.

- **Preparation Phase**: During the second year of *HappyMums* the focus will be progressively shifted to scientific dissemination: the first project results will be presented in scientific conferences or other events organized by stakeholders and published in peer-reviewed journals. Moreover, joint activities with other on-going projects and initiatives in the field will be sought and created.
- Acceptance Phase: During the third year of *HappyMums*, the focus will be on the audiences that require a deeper understanding of *HappyMums* work. These audiences need to be targeted directly, by providing them with the right skills, knowledge and understanding of *HappyMums* tools. This will be achieved through the increase of scientific credibility due to presentations in scientific conferences and scientific articles and the preparation of ad-hoc dissemination materials customized according to the identified targets. In particular, Tommy's and Marce will take care of preparing specific materials targeting women and families. In addition, we will run training events for clinical end-users trialling the prototype system from WP8 within institutional data management systems Those events will provide a template for training events with wider participation once the technology is ready for more general deployment.
- **Commitment Phase:** During the last year of *HappyMums*, the focus will be on sustainability and exploitation of results. Effort will be devoted to dialogue with users (mother and clinicians for the clinical platform and researchers for the research platform) for service expansion and refinement. *HappyMums* tools will be presented to relevant audiences and new clinical guidelines and recommendation specifically devoted to perinatal mental health will be produced. An international final workshop will be organised to promote the project output to all relevant stakeholders, establish the topic in the core agenda of research and innovation at the interface of medicine and engineering, interact with related work in the wider community, and highlight opportunities for future research and innovation. We will invite international speakers from science and industry, as well as potential customers including Clinical Trial Management companies and Clinical Trial units.

The underlying idea is that characteristics and needs of the different target



audiences will evolve with the life and the achievements of the project, and the priority audiences are likely to change. For the time being, the main objective is to make *HappyMums* potential audience aware of its aims and objectives. Following this, potential end-users will be prioritized, whereas towards the end of the project, political stakeholders and the private industry may become the priority audience to target.



3 Communication

Communication will start from the project start-up and will continue during all its stages in order to

- raise citizen engagement;
- support the dissemination and exploitation strategy and, thus, facilitate the uptake of the results;
- foster social and scientific impact of the project results.

For each targeted audience, a distinct strategy using targeted messages, means and language will be planned. Effective mix of both interpersonal and mass communication tools will be used.

In order to support adoption of project results after completion of the project, and potential commercial opportunities, the communication activities take account of prevailing and predicted market conditions. The aim is to prepare the target audiences (including potential users and customers, relevant industry, researchers and strategic partners) for adoption of *HappyMums* results.

The following channels/activities are foreseen:

• **Project website:** it represents the central of communication and dissemination activities. The site will be kept updated with information on project objectives, achievements, progress, results and scientific outcomes, multimedia and other content and it will address diverse type of audience, including general public. The *HappyMums* website is now online and will be maintained by UMIL with continuous updates. English is the official language, but core sections will be translated and reported into partners' local resources. The website leads with a layman's summary defining the motivation, approach, and expected outcomes of the work. It includes a private area of website, accessible only to members of the consortium, which contains non-public data, work-in-progress code, and confidential interim reports.

• **Promotional material:** a "visual identity" of *HappyMums*, including logo, posters, banners and templates for presentations has been created in the first months of the project. Indeed, it is important that *HappyMums* has a recognisable look in order to raise awareness through the website and dissemination material. When people are provided with material at conferences and meetings, they should be able to immediately recognise it as something related to *HappyMums* and be propelled to understand in detail what the network is about. The branding needs to be eye-catching and relevant to science. All material relating to *HappyMmums* will be branded in appropriate manner. For this



reason, an official logo has been created. The logo has been created with the aim to immediately convey the main topic of *HappyMums* (pregnancy, but also neuroscience). Specific templates for text documents and presentations with this logo have been produced and made downloadable for all members of the project. Consistent use of templates ensures a harmonised impression for the project and makes it recognizable.

Figure 1. HappyMums logo.



• Social media: the project will use different social media for the different audience. For example, the *Happymums* Twitter account will be managed by UMIL and will share news related to scientific and professional achievements of the consortium. Facebook and Instagram will be used to propose life habits that could increase resilience and wellbeing and increase awareness of the importance and contribution of biomedical research to the wellbeing of the people. Besides the project official accounts, other social media accounts (Facebook pages, LinkedIn pages Instagram accounts) can be created by specific partners and in different national languages to promote local news.

• **Non-scientific publications**: project news will be published in local and international press to promote the scientific, technical and market-related merits of *HappyMums*.

• **Direct proactive communications and events**: one-to-one communication and attendance to a variety of conferences, trade fairs and exhibitions.

• **Clustering activities**: Relevant initiatives and activities will be identified to establish links. At the moment, strong links are being created with the project funded under the same topic (*HORIZON-HLTH-2021-STAYHLTH-01-02*) to exchange knowledge and best practise, but also to organise joint communication activities. Currently, monthly TCs are being held by the coordinators of all the projects and plans for joint initiatives are being laid down.

• Artistic events: We will organize events, such as dance shows open to the public and specifically targeted to families and lay public and aimed at tackling the issue of mental illness and the associated stigma, using the language of dance. These events will underline the importance of scientific research to get a better understanding of how depression can

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have dramatic consequences in specific key periods of life, such as pregnancy. This will raise public awareness for the project and the EU support.

3.1 Campaign toward women and families

Tommy's, which is a pregnancy charity promoting information around pregnancy issues, will leverage its 'Pregnancy hub' account (Instagram) to increase awareness and engagement with the issue of perinatal mental health and spread news about *HappyMums* amongst women & birthing people. The account will be active from September 2023 onwards.

The contents produced will be shared across the Consortium in order to be translated in other languages and made available by other partners through local resources (Facebook pages, Institutional website etc).

The campaign will consist of Instagram posts (at least twice a month) and will take advantage of initiatives as awareness days and topics around pregnancy, early development, and mental health to drive interest in the project.

The main objectives will be to:

- Raise awareness and reduce stigma of the issue of mental health during and after pregnancy.
- Encourage women to seek support and help if experiencing mental health symptoms in pregnancy.
- Drive at least 3,000 click throughs (with the aim of 150 completed sign-ups in UK) for the feasibility study for the app across Europe during the period of January 2024 to March 2024.
- Introduce the project and its aims in layman's terms to the audience.
- Translate the project progress in layman's terms to the audience.

Specifically, the campaign will have two phases:

- From December 2023 to March 2024: the main goal will be to drive at least 150 women to take part in the feasibility study (Task 5.4)
- From April 2024 to October 2026: the focus will be on building an engaged audience with mental health messaging.

In terms of contents, few key messages have been already identified. In particular:

Perinatal mental health problems are very common, affecting up to 20% (1 in 5) of women at some point during the perinatal period.

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- Perinatal mental health problems have been shown to compromise the healthy emotional, cognitive and even physical development of the child, with serious long-term consequences.
- It is known that mental health problems often occur during the antenatal period and that problems include depression, anxiety, psychosis, post-traumatic stress disorder and other conditions.
- ✓ Maternal depression and anxiety, which often occur together, are at least as common during pregnancy as they are in the year after childbirth.

The wide audience is women and birthing people of reproductive age. For the feasibility study (Jan to Mar 24), the goal is to engage women in early pregnancy during this time as this is the target audience for signups to the study.

For the remainder of the campaign, the goal is to widely target:

- Women.
- Women with mental health conditions who are pregnant or may be considering pregnancy.
- Women thinking about pregnancy.
- Women who had mental health difficulties during pregnancy and now have a baby.

A secondary audience is partners and perhaps wider families/support systems of the above women.

Tommy's employs a team of midwives who could support with videos, advice on mental health support in pregnancy. Moreover, they could reach out to users for their experience of mental health problems in pregnancy.



4 Exploitation

Several scenarios as well as market research related to the exploitation of key exploitable results (KERs) are going to be elaborated and comparatively evaluated within *HappyMums*, with emphasis on long-term sustainability and clear revenue and benefit stream documentation for the stakeholders involved.

The previous long-term experience of several *HappyMums* partners in technologies for data and knowledge management with a socio psychological approach domain (i.e. ABACUS and the University of Barcelona) is an important reference to properly define exploitation scenarios and business strategies, especially based on the different lessons learnt that will be taken into account such as strategies to achieve proper stakeholders' involvement, the critical mass of users and services to reach competitive prices and sustainable economic scales.

The definition of specific scenarios for *HappyMums* KERs will be supported by:

- Promotion of proper ecosystems at European and National level;
- Market identification, assessment of needs by segments with regard to new Medical Guidelines;
- The consortium will implement coordinated and specific actions according to each partner;
- Dissemination and communication are linked to the market penetration actions.

To reach a broad audience and different markets for the project results, the *HappyMums* consortium aims to follow a multi-channel exploitation, where the market and scientific exploitation are linked closely to each other.

The *HappyMums* exploitation strategy will follow different steps:

Exploitation step 1: Definition of KERs

From M9, an in-depth survey amongst all the partners and WP leaders and potential stakeholders will be carried out. Below, a preliminary list of KERs and corresponding exploitation strategy is reported.

KERs	Concept, Target groups, Benefits	
Novel Biomarkers	WHAT: The most relevant biomarkers to be used to develop specific kits	
	for screening.	
	FOR WHOM: Pharma, Biotech, Clinicians/hospitals.	
	WHY: More objective screening, diagnosis and better therapy assessment.	

 Table 4 List of KERs and corresponding exploitation strategy



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Novel therapeutic targets and strategies	 WHAT: Targets for the development of novel drugs or non-pharmacologic therapies. FOR WHOM: Pharma, Biotech Scientific community, supplements industry. WHY: More effective preventive and 'personalized' strategies or therapies. 		
Algorithm to devise the composite score	WHAT: a machine learning model integrating different components.FOR WHOM: Scientists (in the field of precision medicine), clinicians, hospitals.WHY: Patient stratification based on different score profiles.		
Digital platform for new Al-based biomarkers & early signs detection	dashboard.		
Guidelines and Recommendations	WHAT: Informative reports e.g. best practices for diagnosis and treatment. FOR WHOM: Policy makers public and regulatory agencies/clinicians. WHY: improvement of health and social care services.		

Exploitation step 2: Definition of target stakeholders and markets

The consortium will invest efforts to carry out a thorough market analysis and exploitation planning, identifying areas with the highest potential for transferring *HappyMums* multiple KERs. A preliminary analysis is provided in Figure 2, showing a specific list of products, markets, and users for three main stakeholder areas.

Figure 2. HappyMums Preliminary Exploitation analysis

	Healthcare	Industry	Research
	Risk Prediction Algorithm	AI digital platform	New knowledge
Products	Prevention Strategies	Druggable pathways	Data and metadata
Products	Clinical dashboard	Risk Prediction Algorithm	Experimental Protocols
	Clinical Guidelines	Biomarker kits	Publication
	Hospitals	Pharma Companies	University Hospitals
Market	Healthcare Providers	Biotech	Research Institutions
IVIAI KEL	Clinicians	E-Health software SMEs	Funding Bodies
	Public Health agencies	Device Manufacturers	Regulatory bodies
	Clinicians	Patients	Basic Researchers
lleere	Practitioner	Drug developers	Clinical Researchers
Users	Policy makers	Biotech technologists	Public Health Authorities
	Social workers	Biology Labs	Consortium Members

Exploitation step 3: Business planning and IPR management

The *HappyMums* Consortium will follow the approach of cost-benefit analysis and adopt a multi-stakeholder perspective (i.e. costs and benefits will be analyzed separately for

different actors) to correct for optimism bias. The exploitation strategy will build upon this analysis as in Figure 2 to allow the understanding of different users' expectations and main requirements. For market exploration, specific attention will be devoted to the digital platform (App and dashboard) developed by ABACUS, a SME with experience in product development from research project. For this, an initial market analysis will be reported in D 9.2 Exploitation and Business plan version 1, including a specific roadmap for exploitation and protection. During the project, the plan will be updated with a value proposition and a preliminary business model. In the final year of the project, more indepth business studies will be conducted to update the business model, taking advantage of the interaction with users (feedback from women and clinicians in WP5-WP8). The last of the *HappyMums* workshops will include sessions for joint academia-SMEs discussions. Overall, potential economic impact will be quantified for the private sectors, but also for the clinical centres and target European healthcare systems.

To allow effective results exploitation, all consortium partners have the responsibility to share their results obtained during the project to keep them updated about potential interesting findings to disseminate and/or exploit. Prior to making results public, all partners will be notified of contents and timing of the planned dissemination and needed protections (patents) will be secured. Partners can object to (elements of) the intended dissemination in a reasonable timeframe.

The project Consortium Agreement (CA) has now established a legal framework for the project in order to provide clear regulations for issues within the consortium related to the work, IP-Ownership, Access Rights to Background and Results and any other matters of the consortium's interest, providing additional rules regarding ownership of the results.

When CA provisions prove not sufficient, the project Coordinator will collaborate with the IPR departments of the partners involved, building on the experience of previous projects. In addition, specific advice from SESAB members will be sought. If needed, we will consult the IPR Helpdesk of the European Commission.



5 Conclusions

All dissemination and exploitation activities will be performed according to Horizon Europe regulations, including acknowledging funding by Horizon Europe in all publicity about the project and its results.

This document sets the framework for best disseminating the *HappyMums* results to targeted stakeholders. It ensures consistent communication and representation to stakeholders as well as establishing a positive word-of-mouth experience among prospective users. Collaboration among project partners for sharing of results and building on dynamicity and adaptability are key for successful project dissemination and exploitation.